On behalf of GenomeDx Biosciences, we respectfully request the NCCN (Prostate Cancer Guidelines Panel) to review the enclosed data in support for inclusion of the tissue-based molecular assay (Decipher® Prostate Cancer Classifier) for risk stratification of adverse pathology at radical prostatectomy or upon PSA rise/biochemical recurrence.

**Specific Changes**: Recommend adding to adjuvant therapy sections of the guidelines “The 22-marker genomic classifier assay can be considered in men with one or more adverse laboratory/pathologic features or biochemical recurrence for enhanced risk stratification to guide the use of adjuvant or salvage radiotherapy after radical prostatectomy.”

**FDA Clearance**: The Decipher® test is not a FDA-cleared test. Decipher is regulated by the Centers for Medicare & Medicaid Services (CMS) as a CLIA certified Laboratory Developed Test (LDT). Decipher is covered for Medicare beneficiaries (L35650) to enhance risk stratification and measure the risk of metastasis in prostate cancer patients who have pathological stage T2 with a positive surgical margin or pathological stage T3 disease or rising PSA after initial PSA nadir.

**Rationale**: In support of the proposed change, several retrospective analyses suggest that the test may identify patients with good prognosis who may safely avoid adjuvant radiotherapy, the current version of the guideline mentions two tissue-based molecular assays that provide prognostic information beyond NCCN risk assignment that are similar to Decipher®, and it has been validated in over 2,000 patients as reported in 20 peer-reviewed publications.

The following articles are submitted in support of this proposed change.


Sincerely,

Elai Davicioni, PhD
President & CSO
GenomeDx Biosciences
San Diego, CA